IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

Katherine Knox,

Plaintiff,

v.

Johnson & Johnson and Ethicon, Inc.,

Defendants.

Civil Action No. 2:21-cv-156

COMPLAINT AND JURY DEMAND

COMPLAINT

COMES NOW Plaintiff, who by and through the undersigned counsel, hereby submits this Complaint and Jury Demand against Johnson & Johnson and Ethicon, Inc. ("Defendants") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from Plaintiff's injuries from her Ethicon Gynecare Prolift+M and Gynecare TVT-Obturator (TVT-O) pelvic mesh implants manufactured by Defendants. In support of this Complaint, Plaintiff alleges the following.

PARTIES

A. Plaintiff

1. Plaintiff Katherine Knox ("Ms. Knox") is a citizen and resident of Charlotte, Chittenden County, Vermont, and was a citizen and resident of Charlotte, Chittenden County, Vermont at the time she learned of her injuries.

2. All references to "Plaintiff" refer to Tina Marie Knox.

B. Defendants

3. Defendant Johnson & Johnson ("J&J") is a corporation organized and existing under the laws of New Jersey, maintaining its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 089333. J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its pelvic floor repair products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD. J&J is a citizen of New Jersey.

4. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant J&J located in Somerville, New Jersey. Ethicon, Inc. is a corporation organized and existing under New Jersey law, maintaining its principal place of business at 555 US Route 22, Somerville, New Jersey 08876. Ethicon, Inc. is a citizen of New Jersey.

5. J&J and Ethicon, Inc. are collectively referred to herein as "Ethicon" or "Defendants".

6. All acts and omissions of the above-referenced Defendants as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

JURISDICTION AND VENUE

7. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs.

8. Defendants marketed, advertised, and sold the pelvic mesh products at issue in this lawsuit in Vermont, without limitation, and thus have significant contacts with the State of Vermont and this federal judicial district. They therefore are subject to the personal jurisdiction of the Court in this district. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this federal judicial district and therefore, pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

FACTUAL ALLEGATIONS - ETHICON MESH PRODUCTS BACKGROUND

9. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for abdominal hernia repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and SUI.

10. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place

become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

11. Defendants' pelvic mesh products are targeted for women who suffer from pelvic organ prolapse and/or stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

12. Surgical mesh, including mesh used in Gynecare Prolift+M and Gynecare TVT-Obturator (TVT-O) pelvic mesh products, are medical devices that are generally used to repair weakened or damaged tissue. They are made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most pelvic mesh products are comprised of non-absorbable, synthetic, polyester fiber, monofilament polypropylene mesh, polyethylene terephthalate mesh, and/or collagen.

13. Defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The products manufactured by Defendants are considered Class II medical devices.

14. The FDA defines both "degradation" and "fragmentation" as "device

problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

15. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of stress urinary incontinence (SUI). These products included products manufactured, marketed, and distributed by Defendants. These products were approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to Gynecare Prolift+M and Gynecare TVT-Obturator (TVT-O).

16. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Gynecare Prolift+M and TVT-O under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the Gynecare Prolift+M and Gynecare TVT-Obturator (TVT-O) and, thus, a formal review of the safety and efficacy of the Gynecare Prolift+M and Gynecare TVT-Obturator (TVT-O) was never conducted.

CASE SPECIFIC ALLEGATIONS

17. Ms. Knox was implanted with Ethicon's Gynecare Prolift+M (hereinafter "Prolift+M") and Gynecare TVT-Obturator (hereinafter "TVT-O") pelvic mesh products for her stress urinary incontinence and pelvic organ prolapse, serial #PFRA02, #PFRP02, #810081 by Dr. Anne L. Viselli at UVM Medical Center in Knox, Vermont on or about November 9, 2010.

18. Dr. Anne L. Viselli implanted the Gynecare Prolift+M and TVT-O properly and appropriately and in accordance with the instructions for use generated and provided by the Defendants.

19. Ms. Knox subsequently developed complications arising from the implant of the Gynecare Prolift+M and TVT-O mesh product, including worsening mixed incontinence, pelvic pain, dyspareunia, difficulty voiding, dysuria, frequency, nocturia, urinary tract infections, mesh erosion, mesh migration, bleeding, scarring, and urgency.

20. Ms. Knox underwent a surgery performed by Dr. Kris Strohbehn at Dartmouth-Hitchcock in Lebanon, New Hampshire on or about January 15, 2014, during which the Gynecare Prolift+M and TVT-O was removed.

21. Despite removal of the Gynecare Prolift+M and TVT-O, Ms. Knox continues to experience daily complications including, but not limited to, dyspareunia, difficulty voiding, chronic pelvic pain, urinary tract infections, and urgency.

22. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and fraudulent

concealment.

23. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

24. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the Gynecare Prolift+M and TVT-O was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the statute of limitations. Accordingly, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period. Plaintiff did not become aware of the tortious conduct of the Defendants giving rise to her claim, as defined by 12 V.S.A. §512(4), until early 2016. Plaintiff subsequently entered into a tolling agreement with Defendants for her claim, which tolled the applicable statute of limitations from February 23, 2017 until recently. Accordingly, Plaintiff's case has been filed within the applicable statute of limitations.

CAUSES OF ACTION

COUNT I
NEGLIGENCE

25. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 17-24 as if fully set forth herein.

26. Defendants had a duty to individuals, including the Plaintiff, to use

reasonable care in designing, labeling, and selling the Gynecare Prolift+M and TVT-O.

27. Defendants knew or in the exercise of reasonable care should have known, that the Gynecare Prolift+M and TVT-O meshes were not properly designed, labeled, labeled with proper warnings, marketed, sold, and were unreasonably likely to injure its users.

28. Defendants negligently and carelessly designed, labeled, and sold the Gynecare Prolift+M and TVT-O mesh, which they knew or had reason to know was dangerous and unsafe for the use and purpose for which it was intended.

29. Defendants knew or should have known that their Gynecare Prolift+M and TVT-O caused unreasonable, dangerous risks and serious side effects of which Plaintiff would not be aware.

30. Defendants owed a duty of care to Plaintiff and her treating physician, Dr. Anne L. Viselli concerning the Gynecare Prolift+M and TVT-O mesh implanted in Plaintiff and the resulting harm it would cause.

31. Defendants breached their duties to Plaintiff by designing, labeling, and selling the Gynecare Prolift+M and TVT-O that Defendant knew or had reason to know was defective.

32. Defendants breached their aforementioned duty by, among other things:

a. Failing to use reasonable care to utilize reasonably safe design practices in the creation of the Gynecare Prolift+M and TVT-O so as to avoid producing an unsafe finished product, for which it was designed;

b. Failing to use reasonable care to timely and adequately warn

physicians in the field and consumers after discovering potential safety hazards and harms associated with Gynecare Prolift+M and TVT-O;

c. Failing to use reasonable care in providing accurate information, and withholding vital information from patients and their physicians about the propensity of the Gynecare Prolift+M and TVT-O to fail and cause injury and complications;

d. Failing to use reasonable care to timely remove and/or recall from the market to otherwise prevent the continued use of the Gynecare Prolift+M and TVT-O mesh by physicians;

e. Failing to use reasonable care to investigate and/or use known and/or knowable reasonably alternative designs, and/or materials for Defendants' Gynecare Prolift+M and TVT-O mesh;

f. Failing to use reasonable care to make the Gynecare Prolift+M and TVT-O safe and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable;

g. Failing to use reasonable care in designing the Gynecare Prolift+M and TVT-O in which it knew or should have known that the likelihood and severity of potential harm from the Gynecare Prolift+M and TVT-O exceeded the burden of taking safety measures to reduce or avoid harm;

h. Failing to use reasonable care in designing the Gynecare Prolift+M

and TVT-O in which it knew or should have known that the likelihood of potential harm from other devices available for the same purpose;

i. Failing to use reasonable care in designing and establishing a safe, effective procedure for removal for the Gynecare Prolift+M and TVT-O, which can be implemented in the event of a failure, injury, or complication;

j. Failing to use reasonable care in the recruiting and training of physicians and surgeons to implant its Gynecare Prolift+M and TVT-O products and without adequately providing the information about the severity, frequency, and permanency of the risks to those physicians and surgeons;

k. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O when Defendants knew or should have known the mesh was not safe for its intended purpose;

l. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O, consisting of polypropylene material that causes a foreign body immune reaction, which results in adverse effects and injuries;

m. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O that causes foreign body immune reactions, subsequent tissue breakdown, and adverse reactions, such as adhesions to internal organs, once inserted into and

through an area of the body with high levels of bacteria;

n. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O that has the propensity to deform when subject to prolonged tension inside the body;

o. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O that is inelastic, causing it to be improperly mated to the delicate and sensitive areas of the pelvis, which results in pelvic pain during normal daily activities that involve movement in the pelvis (e.g. intercourse, defecation);

p. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O that degrades and fragments over time, causing chronic inflammatory and fibrotic reactions and continuing injuries over time;

q. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O product that has a severe propensity to contract, retract, shrink, erode, extrude, and scar inside the body;

r. Failing to use reasonable care in continuing to design, market, label, and sell the Gynecare Prolift+M and TVT-O product that has a severe risk of recurrent, intractable, permanent pelvic pain and other potential lifelong and debilitating pain resulting from implantation of the Gynecare Prolift+M and TVT-O; and

s. Failing to use reasonable care in continuing to design, market, label,

and sell the Gynecare Prolift+M and TVT-O product that has a need for corrective or revision surgeries to adjust or remove the Gynecare Prolift+M and TVT-O, and that these corrective surgeries may not result in complete resolution of complications, including pain;

33. Prior to implantation of the Gynecare Prolift+M and TVT-O, neither Plaintiff nor her physician, Dr. Anne L. Viselli, were aware of Defendant's negligent conduct, and that Defendant's breached the duty of care by failing to use reasonable care in designing, labeling, and selling the Gynecare Prolift+M and TVT-O.

34. If Plaintiff and her physician Dr. Anne L. Viselli were aware of Defendant's negligent conduct and breach of the duty of care, Plaintiff would not have agreed to undergo the implantation of the Gynecare Prolift+M and TVT-O and Plaintiff would not have suffered her injuries.

35. After implantation of this Gynecare Prolift+M and TVT-O, Plaintiff began experiencing worsening mixed incontinence, pelvic pain, dyspareunia, difficulty voiding, dysuria, frequency, nocturia, urinary tract infections, mesh erosion, mesh migration, bleeding, scarring, and urgency.

36. Plaintiff's post-implantation problems necessitated the need for follow up visits to Plaintiff's physician, as well as an additional surgery, performed by Dr. Kris Strohbehn, to attempt to resolve these complications.

37. Despite additional treatments, Plaintiff continues to suffer daily complications including, but not limited to, dyspareunia, difficulty voiding, chronic pelvic pain, urinary tract infections, and urgency.

38. As a result of Defendant's breach of the duty of care, Plaintiff's Gynecare

Prolift+M and TVT-O failed and caused her injuries.

39. As a direct and proximate result of the breach of duty of care, Plaintiff has experienced significant mental and physical pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, has sustained permanent injuries, including, but not limited to, worsened urinary incontinence, urinary tract infections, injury to her internal organs, sexual dysfunction, scarring, urgency, and pelvic pain. Plaintiff has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services, and other damages. Plaintiff will continue to suffer from these injuries for the remainder of her life and will require her to incur costs and expenses to obtain medical care and purchase products to control and manage her injuries, which would otherwise be unnecessary.

COUNT II
STRICT PRODUCT LIABILITY - DESIGN DEFECT

40. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 17-24 as if fully set forth herein.

41. Gynecare Prolift+M and TVT-O mesh is a permanent polypropylene mesh designed to adhere and integrate into the body without issue. However, its synthetic materials and pore size are criticized as bacterial havens, which in turn leads to numerous injuries including, but not limited to, a higher rate of infections, pain, bleeding, sexual dysfunction, urinary problems, and mesh erosions.

42. The Gynecare Prolift+M and TVT-O implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, these Gynecare Prolift+M and TVT-O

design defects include, but are not limited to:

a. the use of polypropylene material in the Gynecare Prolift+M and TVT-O and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Gynecare Prolift+M and TVT-O to be inserted into and through an area of the body with high levels of bacteria that adhere to the Gynecare Prolift+M and TVT-O causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Gynecare Prolift+M and TVT-O, including, but not limited to, the propensity of the Gynecare Prolift+M and TVT-O to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Gynecare Prolift+M and TVT-O, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Gynecare Prolift+M and TVT-O for migration or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Gynecare Prolift+M and TVT-O, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the hyper-inflammatory responses to the polypropylene mesh leading to problems including chronic pain and fibrotic reaction;

h. the propensity of the polypropylene mesh to disintegrate, erode, and adhere to internal organs after implantation in the female pelvis, causing pain and other adverse reactions;

i. the adverse tissue reactions caused by the polypropylene mesh, which are causally related to infection, as polypropylene is a foreign organic material from animals and/or human cadavers;

j. the harshness of the polypropylene Gynecare Prolift+M and TVT-O upon the female pelvic tissue, and the hardening of the Gynecare Prolift+M and TVT-O in the body.

k. the propensity of the Gynecare Prolift+M and TVT-O for degradation, fragmentation, or erosion over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the Gynecare Prolift+M and TVT-O is implanted according to the manufacturers' instructions.

43. At all times relevant to this action, Defendants developed, designed, labeled, promoted, and sold into the stream of commerce the Gynecare Prolift+M and TVT-O, including the one implanted in Plaintiff.

44. The Gynecare Prolift+M and TVT-O was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when

it left Defendant's possession.

45. The Gynecare Prolift+M and TVT-O implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

46. The Gynecare Prolift+M and TVT-O implanted in Plaintiff was defective in design, in that its risk of harm exceeded its claimed benefits.

47. The Gynecare Prolift+M and TVT-O implanted in Plaintiff was similarly designed, made from the same polypropylene material, and contained all these previously mentioned propensities for failure and injury when it left Defendant's possession.

48. The Gynecare Prolift+M and TVT-O implanted in Plaintiff migrated, and eroded within her body, which necessitated the need for follow up visits to her physician, as well as an additional surgery, performed by Dr. Kris Strohbehn, to attempt to resolve these complications.

49. The Gynecare Prolift+M and TVT-O implanted also caused Plaintiff to suffer unnecessary and prolonged pelvic pain and adverse tissue reactions because the mesh was designed from a polypropylene material that was not reasonably safe for humans.

50. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant.

51. The Defendants could have implemented an alternative design for the Gynecare Prolift+M and TVT-O product by using safer biodegradable polymers, which are less likely to cause inflammatory foreign body responses when implanted because

they are less dense and more absorbable.

52. The Defendants also could have implemented an alternative size for the Gynecare Prolift+M and TVT-O by designing it with larger pores. Larger pore sizes create a lighter pelvic mesh, and in turn, stimulates better integration into the body and reduces foreign body inflammatory responses.

53. Had the Defendants implemented alternative designs for the Gynecare Prolift+M and TVT-O, such as a biodegradable polymer and/or a larger pore size, Plaintiff would not have suffered her injuries.

54. Had the Defendants not used polypropylene material in its Gynecare Prolift+M and TVT-O, Plaintiff would not have suffered foreign body reactions and her subsequent injuries.

55. Plaintiff and Plaintiff's physician, Dr. Anne L. Viselli, used the Gynecare Prolift+M and TVT-O in a manner that was reasonably foreseeable to Defendants.

56. Neither Plaintiff, nor Plaintiff's physician, Dr. Anne L. Viselli, could have, by the exercise of reasonable care, discovered the Gynecare Prolift+M and TVT-O's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with this Gynecare Prolift+M and TVT-O.

57. The Defendants' Gynecare Prolift+M and TVT-O product is dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

58. Defendants are strictly liable to Plaintiff for their defective designing of the Gynecare Prolift+M and TVT-O mesh.

59. As a result of the Gynecare Prolift+M and TVT-O's aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, has sustained permanent injuries, including, but not limited to, worsened urinary incontinence, urinary tract infections, injury to her internal organs, sexual dysfunction, scarring, urgency, and pelvic pain. Plaintiff has undergone medical treatment and will likely undergo further medical treatment and procedures for the rest of her life and will require her to incur costs and expenses to control and manage her injuries, which would otherwise be unnecessary.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

60. Plaintiff re-alleges and incorporates by reference each and every allegation contained in paragraphs 17-24 as if fully set forth herein.

61. Defendants' Gynecare Prolift+M and TVT-O have been and continue to be marketed to the medical community and directly to patients as safe, effective, reliable medical devices with demonstrated long-term clinical results; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

62. Defendants have marketed and sold the Gynecare Prolift+M and TVT-O to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies

include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers.

63. Defendants also utilized documents, patient brochures and websites, offering exaggerated and misleading expectations as to the safety and utility of the Gynecare Prolift+M and TVT-O. Defendants further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

64. Defendants described in its Gynecare Prolift+M and TVT-O Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Gynecare Prolift+M and TVT-O mesh were consistent with any surgical procedure of an implantable medical device and described occurrences of foreign body responses, inflammatory reactions, mesh degradation, and mesh erosions as "minimum to slight" and "transitory", when in fact Defendants knew or should have known that these complications not "minimum to slight", not "transitory", but common, permanent and lifelong, debilitating, and the result of the Gynecare Prolift+M and TVT-O itself and not from surgical procedures.

65. Contrary to Defendants' representations and marketing to the medical community, potential patients, the Plaintiff herself, and Plaintiff's physician Dr. Anne L. Viselli, that the Gynecare Prolift+M and TVT-O was clinically proven, safe, effective, and had demonstrated long-term clinical results, Defendants' Gynecare Prolift+M and TVT-O mesh have high malfunction, failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations,

are difficult to remove, cause sexual dysfunction, urinary tract infections, chronic pelvic pain, stress urinary incontinence, urgency, sarcomas, and have caused severe and irreversible injuries, conditions, and lifelong damages in other patients.

66. Defendants were and are aware that the Gynecare Prolift+M and TVT-O mesh, as described herein, degrades, contracts, shrinks, frays, cords, migrates, stiffens, creates loose pore sizes with tension, causes adverse reactions such as infections, urinary tract infections, chronic pelvic pain, stress urinary incontinence, urgency, sexual dysfunction, sarcomas, and/or otherwise deforms at all times relevant to Plaintiff's claims. Defendants did not place any of these known complications on its pamphlets, booklets, or instructions for use at the time Plaintiff was electing whether to undergo surgery for her stress urinary incontinence and pelvic organ prolapse.

67. The Gynecare Prolift+M and TVT-O implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings to the Plaintiff and her medical provider, Dr. Anne L. Viselli, in order for them to make an informed decision prior to implantation. Such warnings include, but are not limited to:

a. The risk of recurrent, intractable, permanent pelvic pain and other pain resulting from the Gynecare Prolift+M and TVT-O;

b. The need for corrective or revision surgery to adjust or remove the Gynecare Prolift+M and TVT-O;

c. Treatment of stress urinary incontinence or pelvic organ prolapse with

Gynecare Prolift+M and TVT-O is no more effective than feasible available alternatives;

d. Treatment of stress urinary incontinence or pelvic organ prolapse with Gynecare Prolift+M and TVT-O makes future surgical repair more difficult than feasible available alternatives;

e. Removal of the Gynecare Prolift+M and TVT-O due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

f. Complete removal of the Gynecare Prolift+M and TVT-O may not be possible and may not result in complete resolution of the complications, including pain; and

g. The nature, magnitude, and frequency of complications that could arise as a result of implantation of the Gynecare Prolift+M and TVT-O.

68. Ordinary consumers would not have recognized the potential risks and dangers the Gynecare Prolift+M and TVT-O and its polypropylene mesh component posed because its uses were specifically promoted to improve the health of such patients while the nature and prevalence of such risks were either downplayed or not provided to consumers and their physicians.

69. The Gynecare Prolift+M and TVT-O was at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians, including Plaintiff's physician Dr. Anne L. Viselli.

70. Defendants provided incomplete, insufficient, and misleading training

and information to physicians, including Plaintiff's physician Dr. Anne L. Viselli, to increase the number of physicians utilizing the Gynecare Prolift+M and TVT-O regarding its use and aftercare of patients implanted with the Gynecare Prolift+M and TVT-O.

71. Defendants have a post-implant and continuing duty to warn Plaintiff, her medical providers, the medical community, the FDA, and/or the public at large of their Gynecare Prolift+M and TVT-O mesh's known characteristics or defective propensities as described herein. A manufacturer must provide an appropriate warning if there is reasonable evidence of an association of a serious complication with the use of the device. Defendants failed to warn Plaintiff, her medical provider Dr. Anne L. Viselli, the medical community, the FDA, and/or the public. These duties are continuing in nature and will only expire until Defendants permanently remove their products from the market, all medical providers cease implanting Defendants pelvic products into their patients, and/or the FDA bans said products from the market, each of which has yet to occur.

72. Prior to Plaintiff's first surgery on or about November 9, 2010 at UVM Medical Center, Plaintiff and her physician, Dr. Anne L. Viselli, reviewed Gynecare Prolift+M and TVT-O mesh brochures and pamphlets, which stated that the Gynecare Prolift+M and TVT-O mesh was safe, effective, had demonstrated long-term clinical results, and any complications such as foreign body responses, inflammatory reactions, mesh degradation, and mesh erosions were minimum to slight, transitory, and consistent with any surgical procedure.

73. The Plaintiff and Dr. Anne L. Viselli reasonably relied upon and chose

the Gynecare Prolift+M and TVT-O based upon Defendants' physician training and marketing materials, as described herein, regarding the safety, effectiveness, and fitness of their Gynecare Prolift+M and TVT-O mesh. Dr. Anne L. Viselli also lacked independent knowledge of the risks associated with the Gynecare Prolift+M and TVT-O implanted in Plaintiff in order to adequately warn Plaintiff.

74. Plaintiff and Dr. Anne L. Viselli were not made aware that Plaintiff was consenting to these potentially lifelong complications that Defendants did not disclose on its pamphlets, booklets, and instructions for use. Plaintiff and Dr. Anne L. Viselli also had no means and opportunity to discover the true nature of the mesh and its complications prior to implantation.

75. After implantation of this Gynecare Prolift+M and TVT-O, Plaintiff began experiencing severe pelvic pain, dyspareunia, difficulty voiding, dysuria, frequency, worsening mixed incontinence, mesh erosion, mesh migration, bleeding, scarring, and urgency. These complications were never mentioned in Defendant's brochures or pamphlets or otherwise disclosed to Plaintiff and her physician, Dr. Anne L. Viselli, and none of these complications were minimum to slight or transitory as the instructions for use, brochures, and marketing materials indicated. Contrary to Defendant's mesh brochures, pamphlets, and marketing materials, Plaintiff's injuries are permanent and lifelong and caused by the Gynecare Prolift+M and TVT-O itself and not from surgical procedures.

76. These post-implantation problems necessitated the need for follow up visits to Plaintiff's physician, as well as an additional surgery performed by Dr. Kris Strohbehn, to attempt to resolve these complications. Prior to Plaintiff's implantation

surgery, the risks of necessary additional follow-up procedures were known to the Defendant, but not disclosed to Plaintiff or Plaintiff's physician, Dr. Anne L. Viselli.

77. If Plaintiff and her medical provider, Dr. Anne L. Viselli, were aware that these warnings were insufficient or were aware of the true risks associated with the Gynecare Prolift+M and TVT-O, Plaintiff would not have consented to her pelvic mesh surgery, Plaintiff would not have suffered her injuries, and Plaintiff and Dr. Anne L. Viselli would have chosen another course of treatment for her stress urinary incontinence and pelvic organ prolapse such as the Burch colposuspension procedure and sacrospinous ligament suspension procedure, or other procedures without mesh.

78. Defendants are strictly liable to the Plaintiff for failing to warn Plaintiff and Plaintiff's physician, Dr. Anne L. Viselli, of the defects in the Gynecare Prolift+M and TVT-O mesh product.

79. As a result of Defendant's failure to warn as described herein, Plaintiff has experienced significant mental and physical pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, has sustained permanent injuries, including, but not limited to, worsened urinary incontinence, urinary tract infections, injury to her internal organs, sexual dysfunction, scarring, urgency, and pelvic pain. Plaintiff has undergone medical treatment and will likely undergo further medical treatment and procedures for the rest of her life and will require her to incur costs and expenses to control and manage her injuries, which would otherwise be unnecessary.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together

with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries and severe emotional distress sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. restitution and disgorgement of profits;

C. reasonable attorneys' fees;

D. the costs of these proceedings;

E. economic damages;

F. medical monitoring damages;

G. punitive damages; and

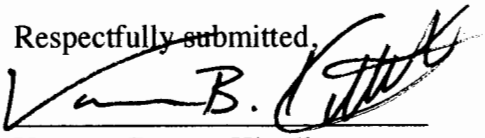
H. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: June 9, 2021

Respectfully submitted,

By: 

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